

PATENT  
Attorney Docket No.: 10139-06302

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: )  
Martin )  
Serial No.: 10/529,139 ) Group Art Unit: 3733  
Filed: May 4, 2006 ) Examiner: J. Sigler  
For: INTRAMEDULLARY NAIL )  
Confirmation No. 2560 )

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In response to the Notification of Non-Compliant Appeal Brief mailed on December 22, 2008 and in support of the Notice of Appeal filed on September 22, 2008, and pursuant to 37 C.F.R. § 41.37, Appellant presents this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 34-60 in the Final Office Action dated May 21, 2008. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Synthes (U.S.A.) which is a wholly-owned Subsidiary of Synthes, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 34-60 have been rejected in the final Office Action and are the subject of this appeal. Claims 1-33 have been cancelled.

4. Status of Amendments

All amendments submitted by the Appellant have been entered.

5. Summary of Claimed Subject Matter

The following summary refers to the specification and identifies certain claim limitations with the reference characters of one or more drawings. The association in this summary of a claim limitation with a particular reference character, figure, or passage from the specification is only exemplary and is not intended to limit the scope of the claims.

The present invention, as exemplified by claim 34, is directed to a an intramedullary nail that includes a nail body having a longitudinal axis 5, a proximal end 1 configured and dimensioned for coupling to an insertion device, and a distal end 2 having a tip 7 configured and dimensioned for insertion into the intramedullary canal of a long bone. (Specification at [0038]; Figure 1). The intramedullary nail also includes at least three transverse holes 3 extending through the distal end 2 of the nail body, each transverse hole 3 defining a hole axis 6, and all three transverse holes 3 grouped at the distal end 2 within a distance  $x$  measured from the tip of the nail body to the axis 6 of the transverse hole 3 furthest from the tip 7. (Specification at [0038]; Figure 1). In this intramedullary nail, a projection of the three hole axes 6 of the at least three transverse holes 3 in a plane orthogonal to the longitudinal axis 5 is such that at least two of the projected hole axes are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and where the distance  $x \leq 25d$ , where  $d$  is either the diameter of the largest of the at least three transverse holes 3 or  $d$  is the mean diameter of the at least three holes 3. (Specification at [0017] and [0039]; Figure 1).

The present invention, as exemplified in claim 45, relates to an intramedullary nail that includes a nail body having a longitudinal axis 5, a proximal end 1 configured and dimensioned for coupling to an insertion device, and a distal end 2 having a tip 7 configured and dimensioned for insertion into the intramedullary canal of a long bone. (Specification at [0038]; Figure 1). The intramedullary nail also includes at least three transverse holes 3 extending through the distal end 2 of the nail body, each transverse hole 3 defining a hole axis 6, and all three transverse holes

3 grouped at the distal end 2 within a distance  $x$  measured from the tip 7 of the nail body to the axis 6 of the transverse hole 3 furthest from the tip. (Specification at [0038]; Figure 1). In this intramedullary nail, a projection of the three hole axes 6 of the at least three transverse holes 3 in a plane orthogonal to the longitudinal axis 5 is such that at least two of the projected hole axes 3 are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and where the distance  $x < 2(n)d$ , where  $n$  is the number of transverse holes 3 grouped within the distance  $x$  from the tip 7 of the nail body and  $d$  is either the diameter of the largest of the at least three transverse holes 3 or  $d$  is the mean diameter of the at least three holes 3. (Specification at [0040]; Figure 1).

The present invention, as exemplified by claim 56, is directed to an intramedullary nail that includes a nail body having a longitudinal axis 5, a proximal end 1 configured and dimensioned for coupling to an insertion device, and a distal end 2 having a tip 7 configured and dimensioned for insertion into the intramedullary canal of a long bone. (Specification at [0038]; Figure 1). The intramedullary nail also includes at least three transverse holes 3 extending through the distal end 2 of the nail body, each transverse hole 3 defining a hole axis 6, and all three transverse holes 3 grouped at the distal end 2 within a distance  $x$  measured from the tip 7 of the nail body to the axis 6 of the transverse hole furthest from the tip 7. (Specification at [0038]; Figure 1). A projection of the three hole axes 6 of the at least three transverse holes 3 in a plane orthogonal to the longitudinal axis 5 is such that at least two of the projected hole axes 6 are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and where a distance  $a$  between the tip 7

and the transverse hole 3 closest to the tip is  $a \leq 5 d$ , where  $d$  is the diameter of the transverse hole 3 closest to the tip 7. (Specification at [0009] and [0026]).

6. Grounds of Rejection to be Reviewed on Appeal

1. Whether claims 34-52 and 54-60 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,551,321 to Burkinshaw et al. in view of U.S. Patent No. 6,120,504 to Brumback et al. and U.S. Patent No. 6,296,645 to Hover et al.

II. Whether claim 53 is unpatentable under 35 U.S.C. § 103(a) over Burkinshaw in view of Brumback, Hover, and U.S. Patent No. 5,458,654 to Tepic.

7. Argument

Claims 34 - 52 and 54 - 60 stand rejected under 35 U.S.C. 103(a) as unpatentable over Burkinshaw et al. (U.S. Patent No. 6,551,321) in view of Brumback et al. (U.S. Patent No. 6,120,504) and Hover et al. (U.S. Patent No. 6,296,645).

Claim 34 recites an intramedullary nail comprising “a nail body having a longitudinal axis, a proximal end configured and dimensioned for coupling to an insertion device, and a distal end having a tip configured and dimensioned for insertion into the intramedullary canal of a long bone” in combination with “at least three transverse holes extending through the distal end of the nail body, each transverse hole defining a hole axis, and all three transverse holes grouped at the

distal end within a distance  $x$  measured from the tip of the nail body to the axis of the transverse hole furthest from the tip, wherein a projection of the three hole axes of the at least three transverse holes in a plane orthogonal to the longitudinal axis is such that at least two of the projected hole axes are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and *where the distance  $x \leq 25d$ , where  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes.*

As stated previously, the Examiner has tacitly admitted that none of the cited references shows or suggests a distance  $x$  between the tip and a furthest hole axis  $\leq 25d$  “*where d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes*,” as recited in claim 34. Specifically, to show this claim element, the Examiner has relied solely on measurements of Fig. 6 of Burkinshaw which he concedes does not state that its drawings are to scale and which is silent as to dimensions. The MPEP specifically states that “arguments based on measurements of the drawing features are of little value.” (MPEP § 2125). “[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.” Hockerson-Halberstadt, Inc. v. Avia Group, Int'l, 222 F.3d 951, 956 (Fed. Cir. 2000) (quoted in MPEP § 2125).

Further, the Examiner also concedes that Burkinshaw does not specifically teach the holes being within 25 hole-diameters from the tip ( $x \leq 25d$ ), nor does Burkinshaw show or suggest a range for the hole diameter or any relation between hole diameter and a distance from the tip of

the nail. The Examiner goes on to state that “[i]t would have been obvious to use a known screw, having 4.5 mm as the outer diameter, in the invention of Burkinshaw et al., since one would have chosen from among suitable diameters for screws in the art as such as the one suggested by Hover et al.” Initially it is noted that this speculation leads to the claimed positioning of the holes only when coupled with a further unsupported speculation – i.e., the initial speculation that the drawings are drawn to scale to show the positions of the holes relative to the distal tip. Furthermore, it is respectfully submitted that these speculations necessitates the further speculation that any change in screw diameter would not have resulted in further changes to the placement of the screw holes the positions of which are already so imperfectly established in the Examiner’s rejection.

In support of this rejection, the Examiner refers to the dimensions Burkinshaw discloses, which include the lengths and diameters of the filament bundles and the overall length of the rod assembly. (See Burkinshaw, col. 4 ln. 65 - col. 5 ln. 3). It is noted that the embodiments disclosed in Burkinshaw “provide *an intramedullary nail constructed from an assembly of multiple rods, wires or filaments attached at both ends by end caps.*” (*Id.*, col. 4 ln. 53-56). The overall length which the Examiner refers to is the “*overall length of the rod assembly*” which Burkinshaw explains can be from 18 cm - 55 cm. From the language in Burkinshaw, it is evident that the rod assembly comprises only part of the intramedullary nail. Burkinshaw only discloses a range of overall lengths for the rod assembly which comprises the cage portion of the intramedullary nail. The overall length of the entire intramedullary nail is the sum of the lengths of the two end caps

and the length of the rod assembly. It seems the Examiner has assumed that the overall length of the rod assembly is equivalent to the overall length of the entire intramedullary nail. In that case, such an assumption would be an improper interpretation of the specification as disclosed by Burkinshaw, because it is clear from the specification of Burkinshaw that the rod assembly comprises only a portion of the entire intramedullary nail.

Furthermore, it is submitted that Burkinshaw includes no showing or suggestion of "at least three transverse holes extending through the distal end of the nail body," as recited in claim 1. Nor does Burkinshaw show or suggest that "a projection of the three hole axes of the at least three transverse holes in a plane orthogonal to the longitudinal axis is such that at least two of the projected hole axes are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ ," as recited in claim 1.

For these reasons it is respectfully submitted that the Examiner's rejection constitutes an improper hindsight reconstruction of the invention and that none of the cited references either shows or suggests "*at least three transverse holes in a plane orthogonal to the longitudinal axis ... are at [a]...distance x ≤ 25d, where d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes*," as recited in claim 34 and that this claim is allowable over Burkinshaw, Brumback and Hover taken either alone or in combination. Because claims 35 - 44 depend on and therefore include the limitations of claim 34, it is respectfully submitted that these claims are also allowable.

Claim 45 recites claims substantially similar to claim 34 including “*the distance x < 2(n)d, where n is the number of transverse holes grouped within the distance x from the tip of the nail body and d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes.*” Therefore, it is respectfully submitted that claim 45 and its dependent claims 46-55 are also allowable over Burkinshaw, Brumback, and Hover for at least the same reasons previously mentioned with regard to claim 34.

Claim 56 also recites claims substantially similar to claim 34 including “*a distance a between the tip and the transverse hole closest to the tip is a < 5 d.*” Thus, it is respectfully submitted that claim 56 and its dependent claims 57 - 60 are also allowable over Burkinshaw, Brumback, and Hover for at least the same reasons previously mentioned with regard to claim 34.

Claim 53 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Burkinshaw in view of Brumback and Hover and in further view of Tepic (U.S. Patent No. 5,458,654) (hereinafter “Tepic”).

Appellant respectfully submits that Tepic fails to cure the above mentioned deficiencies of Burkinshaw and that Burkinshaw, Brumback, Hover, and Tepic, taken alone or in any combination, fail to teach “*the distance x < 2(n)d, where n is the number of transverse holes grouped within the distance x from the tip of the nail body and d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes*”

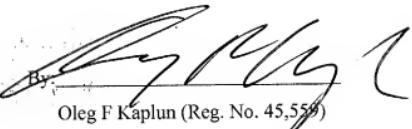
as recited in claim 45. Therefore, it is respectfully submitted that claim 45 and its dependent claims 46 - 55 are allowable over Burkinshaw, Brumback, Hover, and Tepic.

8. Conclusions

For the reasons set forth above, Appellant respectfully requests that the Board reverse the final rejection of the claims by the Examiner and indicate that all pending claims are allowable.

Respectfully submitted,

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CLAIMS APPENDIX

1 - 33. (Canceled)

34. (Previously presented) An intramedullary nail comprising:

a nail body having a longitudinal axis, a proximal end configured and dimensioned for coupling to an insertion device, and a distal end having a tip configured and dimensioned for insertion into the intramedullary canal of a long bone,

at least three transverse holes extending through the distal end of the nail body, each transverse hole defining a hole axis, and all three transverse holes grouped at the distal end within a distance  $x$  measured from the tip of the nail body to the axis of the transverse hole furthest from the tip,

wherein a projection of the three hole axes of the at least three transverse holes in a plane orthogonal to the longitudinal axis is such that at least two of the projected hole axes are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and where the distance  $x \leq 25d$ , where  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes.

35. (Previously presented) The nail of claim 34, where the distance  $x \leq 7d$ .

36. (Previously presented) The nail of claim 34, wherein at least two of the projected hole axes are at an angle  $\alpha$  of  $58^\circ \leq \alpha \leq 62^\circ$ .

37. (Previously presented) The nail of claim 34, wherein at least two of the projected hole axes are at an angle  $\alpha$  of  $59^\circ \leq \alpha \leq 61^\circ$ .

38. (Previously presented) The nail of claim 34, wherein at least two of the projected hole axes are at an angle  $\alpha$  of  $43^\circ \leq \alpha \leq 47^\circ$ .

39. (Previously presented) The nail of claim 34, wherein at least two of the projected hole axes are at an angle  $\alpha$  of  $44^\circ \leq \alpha \leq 46^\circ$ .

40. (Currently Amended) The nail of claim 34, wherein at least two of the projected hole axes are at an angle  $\alpha$  of  $35^\circ \leq \alpha \leq 37^\circ$ .

41. (Previously presented) The nail of claim 34, wherein at least two of the projected hole axes are at an angle  $\alpha$  of  $35.5^\circ \leq \alpha \leq 36.5^\circ$ .

42. (Previously presented) The nail of claim 34, wherein at least two of the projected hole axes are at an angle  $\alpha$  of  $29^\circ \leq \alpha \leq 31^\circ$ .

43. (Previously presented) The nail of claim 34, wherein at least two of the projected hole axes are at an angle  $\alpha$  of  $29.5^\circ \leq \alpha \leq 30.5^\circ$ .

44. (Previously presented) The nail of claim 34, further comprising at least a fourth hole grouped at the distal end of the nail body within the distance  $x$  measured from the tip of the nail body to the axis of the transverse hole furthest from the tip.

45. (Previously presented) An intramedullary nail comprising:

a nail body having a longitudinal axis, a proximal end configured and dimensioned for coupling to an insertion device, and a distal end having a tip configured and dimensioned for insertion into the intramedullary canal of a long bone,

at least three transverse holes extending through the distal end of the nail body, each transverse hole defining a hole axis, and all three transverse holes grouped at the distal end within a distance  $x$  measured from the tip of the nail body to the axis of the transverse hole furthest from the tip,

wherein a projection of the three hole axes of the at least three transverse holes in a plane orthogonal to the longitudinal axis is such that at least two of the projected hole axes are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and where the distance  $x < 2(n)(d)$ , where  $n$  is the number of transverse holes grouped within the distance  $x$  from the tip of the nail body and  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes.

46. (Previously presented) The intramedullary nail of claim 45, wherein the distance  $x < 1.8(n)(d)$ .

47. (Previously presented) The intramedullary nail of claim 45, wherein the distance  $x < 1.5(n)(d)$ .

48. (Previously presented) The intramedullary nail of claim 45, wherein the distance  $x < 1.4(n)(d)$

49. (Previously presented) The intramedullary nail of claim 45, wherein the distal end of the nail includes at least five transverse holes grouped within the distance  $x$ , such that  $n = 5$ .

50. (Previously presented) The intramedullary nail of claim 45, wherein at least two of the transverse holes at least partially intersect one another.

51. (Previously presented) The intramedullary nail of claim 50, wherein the at least two intersecting transverse holes are spaced at an angle  $\alpha$  of  $88^\circ - 92^\circ$  with respect to one another.

52. (Previously presented) The intramedullary nail of claim 45, wherein at least one of the transverse holes includes an internal thread.

53. (Previously presented) The intramedullary nail of claim 45, wherein at least one of the transverse holes includes at least a portion with a conical shape.

54. (Previously presented) The intramedullary nail of claim 45, wherein the nail body has a tubular cross-section.

55. (Previously presented) The intramedullary nail of claim 45, wherein the axes of all transverse holes are located in planes orthogonal to the longitudinal axis of the nail body.

56. (Currently Amended) An intramedullary nail comprising:

a nail body having a longitudinal axis, a proximal end configured and dimensioned for coupling to an insertion device, and a distal end having a tip configured and dimensioned for insertion into the intramedullary canal of a long bone,

at least three transverse holes extending through the distal end of the nail body, each transverse hole defining a hole axis, and all three transverse holes grouped at the distal end within a distance  $x$  measured from the tip of the nail body to the axis of the transverse hole furthest from the tip.

wherein a projection of the three hole axes of the at least three transverse holes in a plane orthogonal to the longitudinal axis is such that at least two of the projected hole axes are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and where a distance  $a$  between the tip and the transverse hole closest to the tip is  $a \leq 5 d$

where  $d$  is the diameter of the transverse hole closest to the tip.

57. (Previously presented) The intramedullary nail of claim 56, wherein the distance  $a \leq 1.5 d$ .

58. (Previously presented) The intramedullary nail of claim 56, wherein a plurality of  $n$  transverse holes are located in the nail body, and a center of each hole is located at a distance  $x$  from the tip of the nail body, where  $1.05(n)(d) \leq x \leq 3.0(n)(d)$ .

59. (Previously presented) The intramedullary nail of claim 58, where  $x < (4(d) + (n-1)(2.2d))$ .

60. (Previously presented) The intramedullary nail of claim 56, wherein a distance  $b$  between the axes of two adjacent transverse holes is  $b \leq 1.5 d$ .

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**EVIDENCE APPENDIX**

No evidence has been entered or relied upon in the present appeal.

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**RELATED PROCEEDING APPENDIX**

No decisions have been rendered regarding the present appeal or any proceedings related thereto.

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